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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,028	04/26/2005	George D Hartman	20942P	2202
210	7590	04/21/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			RAO, DEEPAK R	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 04/21/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,028	HARTMAN ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,14-16,19-23,39 and 40 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,14-16,19-23,39 and 40 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>101905 & 122705</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-10, 14-16, 19-23 and 39-40 are pending in this application.

Specification

The disclosure is objected to because of the following informalities:

Some of the specification pages contain illegible text, see particularly pages 4, 10, 16, 22, 28, 34, 40, 46, 52, 58, 70, 76, 82. (A representative portion of page 4 is provided below as an example):

carc. Kamb, A. et al. (1994) *Science* 264, 436-440, Nobori, et al. (1994) *Nature* 368, 753-756, Spruck, C.H. et al. *Nature* 370, 183-184, Hunter, T. and Pines, J. (1991) *Cell* 66, 1071-1074, Keyomarsi, K. and Pardee, A.B. (1993) *Proc. Natl. Acad. Sci. U.S.A.* 90, 1112-1116 and Wang, T.C. (1994) *Nature* 369, 669-671.

Members of the cyclin dependent kinase family include Cdk2 and Cdk4. Both are on the G₁ phase of cell cycle and regulate entry into the G₁/S phase transition. In one pathway, these kinases regulate the phosphorylation of the retinoblastoma protein. Substrate phosphorylation releases the E2F transcription factor which in turn regulates the expression of required for S phase entry. Inhibition of these kinases, therefore, blocks cell entry into the and downstream proliferative events.

Small molecular cyclin dependent kinase inhibitors have already been identified and shown to have growth inhibitory activity against a number of different tumor types *in vitro* and *in vivo*. Glab, N. et al. (1994) *FEBS Lett.* 353, 207-211, Kitagawa, M. et al. (1993) *Oncogene* 8, 2425-2432, Losiewicz, M.D. et al. (1994) *Biochem. Biophys. Res. Commun.* 201, 589-595, Carlson, B.A. et al. (1996) *Cancer Res.* 56, 2973-2978, Kelland, L.R. (2000) *Expert Opin. Invest. Drugs* 9, 2903-2911 and Senderowicz, A.M. (1999) *Invest. New Drugs* 17, 313-320.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-16, 19-23 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating lung adenocarcinoma, does **not** reasonably provide enablement for a method of treating all other types of cancer generally; a method of **preventing** cancer generally; a method of treating or **preventing** a disease in which angiogenesis is implicated; a method of treating or **preventing** retinal vascularization, diabetic retinopathy, or age-related macular degeneration; or a method of treating or **preventing** cancer by administering a compound according to the invention in combination with a second compound and/or radiation therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

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The instant claims 39-40 are drawn to 'a method of treating or preventing cancer which comprises a therapeutically effective amount of a compound of formula I in combination with a second compound selected from an estrogen receptor modulator, anti-proliferative agent, another angiogenesis inhibitor and/or radiation therapy' and the specification pages 36-37 provide some examples of the additional therapeutic agent intended by the claim, however, the scope of the claim includes therapeutic agents that are known and those that may be discovered in future, for which there is no enablement. Further, the entire scope of the therapeutic activity intended for the compounds of the invention is not enabled for the reasons provided below.

The instant claims 15-16 are drawn to 'a method of treating or preventing cancer'; claims 19-20 are drawn to 'a method of treating or preventing a disease in which angiogenesis is implicated' and the specification at pages 13-14 provides a wide variety of conditions for which the instant compounds may be used as therapeutic agents. The specification at pages 43-50 provides *in vitro* assays to measure the VEGF, FLT-1, FLT-3, CDK4 and CDK2 kinase inhibition activity. Based on the tyrosine kinase inhibition activity, the specification provides that the compounds are useful in the treatment of tyrosine kinase-dependent diseases and conditions such as angiogenesis, cancer, tumor growth, age related macular degeneration, diabetic retinopathy, etc. The instant claims appear to be 'reach through' claims. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention.

The testing assays provided in the specification on pages 43-50 are related to some select

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types of protein kinase inhibition, the instant claims on the other hand are drawn to ‘method of treating or preventing cancer; or a disease in which angiogenesis is implicated; etc.’. There is neither data on how many compounds were tested nor data on which enzymes were inhibited and which ones were not. Applicant did not state on record or provide any guidance that the assays provided are correlated to the clinical efficacy of the treatment of various disorders of the claims. As can be seen from specification pages 34-37, the *in vitro* data holds significant role in determining the dosage regimen based on the minimal effective concentration of each of the compound to achieve the desired inhibition of the tyrosine kinases.

The instant claims are drawn to “a method treating or preventing cancer, a disease in which angiogenesis is implicated, retinal vascularization, diabetic retinopathy, age-related macular degeneration, etc.” First, the instant claims cover ‘diseases’ that are known to exist and those that may be discovered in the future, for which there is no enablement provided. The use disclosed in the specification is as tyrosine kinase inhibitors, in the treatment of a laundry list of diseases, which include cancer, inflammatory diseases, bone associated diseases, etc. Test assays and procedures are provided in the specification in pages 43-50, related to select types of protein kinase inhibition and it was concluded that the compounds of the invention exhibit inhibitory activity, however, there is nothing in the disclosure regarding how this *in vitro* data correlates to the treatment of the diverse disorders of the instant claims. The diseases and disorders encompassed by the instant claims include various types of cancer, inflammatory diseases, angiogenesis, etc., some of which have been proven to be extremely difficult to treat. Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as

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to be chemically non-equivalent and there is no basis in the prior art for assuming the same.

Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Further, the instant claims recite treating of diseases mediated by various types of protein kinases, and there is no disclosure regarding how all these assorted types diseases are treated. See MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art. Receptor activity is generally unpredictable and highly structure specific area, as evidenced by the wide range of results obtained for the tested compounds. It is inconceivable as to how the claimed compounds can treat the large list of diseases embraced by the claims having diverse mechanisms. The state of the art is indicative of the unpredictability of the therapeutic approach based on kinase inhibiting activity. Cressey et al. (Medline Abstract 2005) state that “Although numerous publications dealing with the measurement of circulating VEGF for diagnostic and therapeutic monitoring have been published, the relationship between the production of tissue VEGF and its concentration in blood is still unclear”.

The instant claims are further drawn to ‘treating or preventing cancer, tumor growth’. A ‘cancer’ or ‘tumor growth’ is anything that causes abnormal tissue growth. That can be growth by cellular proliferation more rapidly than normal, or continued growth after the stimulus that initiated the new growth has ceased, or lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such term covers not only all cancers, but also covers precancerous conditions such as lumps, lesions, polyps, etc. No compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a “silver bullet” is contrary to our

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present understanding of oncology. For example, Yano et al. (Medline Abstract 2000) provides for the treatment of malignant pleural effusion of human lung adenocarcinoma by inhibition of VEGF receptor, however, the state of the art is not indicative any pharmaceutical agents that are useful in the treatment or prevention of cancer generally. Cecil Textbook of Medicine states that “each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study” (see the enclosed article, page 1004). Different types of cancers affect different organs and have different methods of growth and harm to the body. Also see *In re Buting*, 163 USPQ 689 (CCPA 1969), wherein ‘evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers’. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally. In reference to cancer treatment using protein tyrosine kinase inhibitors, Traxler (Exp. Opin. Ther. Patents, 1997) stated that “pharmacological properties such as stability in biological media, bioavailability, metabolism or formulability are significant hurdles” see page 585, col. 2, lines 33-36.

The claims recite the use of the instantly claimed compounds in treating 'a disease in which angiogenesis is implicated'. Angiogenesis is the process of vascularization of a tissue involving the development of new capillary blood vessels and therefore, is not seen as being a disease or disorder, but as an absolutely essential body process. Thus, there is no enablement for treating something which is not itself a problem and is indeed essential for life.

The claims recite the use of the instantly claimed compounds in 'treating age-related macular degeneration'. A state of the art reference, Roodhooft (PubMed Abstract enclosed) provides that 'there is no efficacious treatment for age-related macular degeneration'.

The diagnosis of each of the disease is generally suggested by medical history and reports of endoscopy, cytology, X-ray, biopsy, etc. depending on the symptoms, signs and complications, which is essential to establish the dosage regimen for appropriate treatment or prevention. The disclosure does not provide any guidance towards the dosage regimen required to facilitate the treatment and/or inhibition of the claimed disorders, nor indicate competent technical references in the appropriate methods.

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, “the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved”. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Traxler, in a recent article (Exp. Opin. Ther. Patents, 1997) stated that “The concept of the inhibition of growth factor receptor-mediated signal transduction via inhibition of its protein tyrosine kinase is a novel, **not yet proven** clinical approach to the regulation of cell proliferation”, see page 585, col. 1. Therefore, the state of the art provides the need of undue experimentation for the instantly claimed therapeutic benefits.

(Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements).

The instant claims are also drawn to ‘a method of **preventing**’ of various the diseases or conditions and therefore, the instant claim language includes 'prevention' of the recited disorders in a subject, which is not remotely enabled. 'To prevent' actually means *to anticipate or counter*

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in advance, to keep from happening etc. (as per Websters II Dictionary) and therefore it is not understood how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the “preventive” effect. It is inconceivable from the *in vitro* data of a small number of representative compounds can be correlated to the ‘treatment and prevention’ of the conditions recited in the claims, such that the claimed compounds can not only treat but also “prevent” the disorders or conditions of the instant claims. Further, there is no evidence on record which demonstrates that the *in-vitro* screening test relied upon is recognized in the art as being reasonably predictive of success in any of the contemplated areas of ‘prevention’. Such a reasonable correlation is necessary to demonstrate such utilities. See *Ex parte Stevens*, 16 USPQ 2d 1379 (BPAI 1990); *Ex parte Busse et al.*, 1 USPQ 2d 1908 (BPAI 1986) (the evidence must be accepted as “showing” such utility, and not “warranting further study”).

MPEP § 2164.01(a) states that “A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)”. That conclusion is clearly justified here and undue experimentation will be required to practice the claimed invention.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples

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regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 14-16, 19-23 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Bilodeau et al., WO 02/45652 (published June 13, 2002). The instant claims read on reference disclosed compounds, see the compounds of structural formula I in page 5 and the corresponding species of compounds 19-3 and 19-4 (in page 90). The reference compounds are taught to be useful as tyrosine kinase inhibitors, see the abstract.
2. Claims 1-4, 14-16, 19-23 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Das et al., WO 00/62778 (published October 26, 2000). The instant claims read on reference disclosed compounds, see the compounds of structural formula I in page 3 and the corresponding species of Examples 444-472. The reference compounds are taught to be useful as tyrosine kinase inhibitors, see the abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-4, 14-16, 19-23 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das et al., WO 00/62778. The reference teaches a generic group of pyrimidine compounds, which embraces applicant's instantly claimed compounds. See formula I in page 3, and the corresponding species of Examples 444-472. The reference compounds are taught to be useful as tyrosine kinase inhibitors, see the abstract. The instant claims are anticipated by the reference compounds as indicated above in the rejection under 35 U.S.C. 102(b). Alternatively, the instant claims differ from the reference by reciting specific species or a more limited subgenus than the reference. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable

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expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

2. Claims 1-10, 14-16, 19-23 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilodeau et al., WO 02/45652. The reference teaches a generic group of pyrimidine compounds, which embraces applicant's instantly claimed compounds. See the compounds of structural formula I in page 5 and the corresponding species of compounds 19-3 and 19-4 (in page 90). The reference compounds are taught to be useful as tyrosine kinase inhibitors, see the abstract. Claims 1-4, 14-16, 19-23 and 39-40 are anticipated by the reference, see the rejection under 35 U.S.C. 102 above. The remaining claims 5-10 differ from the reference by reciting specific species or a more limited subgenus than the reference. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the

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claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 14-16, 19-23 and 39-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12-15, 17-18, 20-21, 23, 26-33, 40 and 44-46 of copending Application No. 10/677,687. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims substantially overlap the reference claims. The reference claims are drawn to a generic group of pyrimidine compounds, which embraces applicant's instantly claimed

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compounds. See formula I in claim 1. The reference compounds are taught to be useful as pharmaceutical agents, see claims 12-15, 17-18, etc. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have had the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Receipt is acknowledged of the Information Disclosure Statements filed on October 19 and December 27, 2005 and copies are enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deepak Rao
Primary Examiner
Art Unit 1624

April 14, 2006